K031051

FEB 2 0 2004

INTELLIGENT HEARING SYSTEMS

510(k) Summary

Prepared By:	Intelligent Hearing Systems 7356 SW 48th Street Miami, FL 33155
Telephone:	(305) 668-6102
FAX:	(305) 668-6103
Contact Person:	Edward Miskiel, Ph.D.
Date Summary prepared:	February 13, 2004
Name of the Device:	SmartEP-ASSR
Common Name:	Evoked Response System
Classification Name:	Evoked Response Auditory Stimulator (per CFR 874.1900)
Predicate Device:	Bio-logic MASTER Evoked Response System (K021895)
Device Description:	SmartEP-ASSR is a auditory evoked potential testing device that is capable of measuring auditory steady state responses (ASSR).
Intended Use:	The intended use of the SmartEP-ASSR product is for the recording of auditory steady-state evoked potential data. The product is intended to be used as a diagnostic aid in auditory and hearing related disorders and as an adjunctive tool in the estimation of behavioral hearing thresholds. SmartEP-ASSR can be used for patients of all ages. It is intended to be used by trained personnel in a hospital, nursery, clinic, audiologist's office or other appropriate setting.
Technological Characteristics:	The SmartEP-ASSR device is similar to the predicate device in its intended use and data processing methodologies.

Substantial Equivalence Based on Assessment of Performance Data:

The SmartEP-ASSR is substantially equivalent to the Bio-logic MASTER Evoked Response System device marketed by Bio-logic Systems Corp. with FDA 510(k) clearance number K021895. Comparisons of technical parameters are shown in the table below.

Parameter	Predicate Device (Non-Preamendmant Device) *Bio-Logic Master (K021895)*	Device Under Current 510(k) Review *SmartEP-ASSR*
Data Acquisition		
A/D Resolution	16 bit	16 bit
Artifact Rejection	Programmable	Programmable
Amplifiers		
Channels	1 Channel Optically Isolated	1-4 Channels Optically Isolated
Gain	10k	Variable (30k-300k)
Filters		
Slope	12 dB/octave	6 dB/octave
LP	1.5k, 3k, 10k, 20k Hz	30, 100, 300, 500, 1k, 1.5k, 3k, 5k Hz
HP	0.1, 0.3, 1, 3, 10, 30, 100, 300Hz	1, 10, 30, 50, 100, 150, 300, 500 Hz
Notch	50/60Hz	50/60Hz
Digital Filters	1-200Hz	User Selectable (1 -5k Hz)
Noise Level	0.45 µV RMS (10-3k Hz)	0.33 µV RMS (1-3k Hz)
Input Impedance	100M Ohms	5M Ohms
CMR Ratio	110 dB at 50/60 Hz	117 dB at 60 Hz and 110 dB at 1k Hz
Impedance Test		
Signal	20 Hz Sinewave	1k Hz Sinewave
Auditory Stimuli		
Presentation	Monaural or Binaural	Monaural or Binaural
Number of Frequencies	1-4	1-8
Test Frequencies	500, 750, 1k, 1.5k, 2k, 3k, 4k, 6k, 8k Hz	User Selectable: Clicks, Pure Tones and Multifrequency Stimuli (500Hz-8k Hz)
Types	Sinewave	Sinewave, Tone Burst

Envelopes	Linear, Blackman, Gaussian, Hanning Envelopes	Linear, Blackman, Gaussian, Hanning, Rectangular, Triangular, Trapezoidal, Exact Blackman, Cosine, Cosine Squared, Cosine Cubed
Intensity	0-125 dB SPL (132 dB Optional)	0-125 dB SPL
Masking	White Noise Programmable	White Noise Programmable
Transducers	TDH Earphones, Insert Earphones, Bone Conduction, Sound Field	TDH Earphones, Insert Earphones, Bone Conduction, Sound Field, OAE Probe
Computer Requirements		
Computer Type	Personal Computer	Personal Computer
Operating System	Microsoft Windows	Microsoft Windows 98SE, ME, 2000, XP
Interface Connection	Serial	USB (Universal Serial Bus)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 0 2004

Edward Miskiel, Ph.D.
President and CEO
Intelligent Hearing Systems
7356 S.W. 48th Street
Miami, Florida 33155

Re: K031051
Trade/Device Name: SmartEP- ASSR
Regulation Number: 21 CFR 882.1900
Regulation Name: Evoked response auditory stimulator
Regulatory Class: II
Product Code: GWJ
Dated: December 18, 2004
Received: December 23, 2004

Dear Dr. Miskiel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K031051

Device Name: SmartEP-ASSR

Indications For Use:

The intended use of the SmartEP-ASSR product is for the recording of auditory steady-state evoked potential data. The product is intended to be used as a diagnostic aid in auditory and hearing related disorders and as an adjunctive tool in the estimation of behavioral hearing thresholds.

SmartEP-ASSR can be used for patients of all ages. It is intended to be used by trained personnel in a hospital, nursery, clinic, audiologist's office or other appropriate setting.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhorn

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K031051